K060815

4. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

4.1 MANUFACTURING FACILITY

APR 18 2006

BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126

Contact Person: James S. Miller
Vice President
Regulatory Affairs and Quality Assurance
262-835-3300

4.2 TRADE NAME

Juliesse™ Injectable Laryngeal Augmentation Implant

4.3 INTENDED USE

BioForm's Juliesse is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months.

4.4 PRODUCT DESCRIPTION

Juliesse is a sterile, non-pyrogenic injectable material consisting of an aqueous formulation of USP grade pharmaceutical excipients consisting of sterile water, glycerin, sodium carboxymethylcellulose and phosphate buffer. These excipients have prior and extensive use in intramuscular injectable pharmaceutical products including Cortone, Decadron and Dalalone drugs. Glycerin, sodium carboxymethylcellulose and phosphate buffer are listed in 21 CFR 182 as Generally Recognized as Safe (GRAS), Sections 182.1320 182.1745, and 182.6285, respectively.

4.5 SUBSTANTIAL EQUIVALENCE

The following is the predicate device that is substantially equivalent to Juliesse™ Injectable Laryngeal Augmentation Implant:

K033398
Radiesse™ Voice Gel Injectable Laryngeal Augmentation Implant
BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126

4.6 BIOCOMPATIBILITY EVALUATIONS

The battery of preclinical safety studies and animal implant studies show that the Juliesse™ Injectable Laryngeal Augmentation Implant is biocompatible when injected into soft tissues.

4.7 STERILIZATION

Juliesse™ Injectable Laryngeal Augmentation Implant is sterilized using steam; processing is performed in-house using a computer controlled autoclave system. Cycle parameters were validated using an overkill methodology to 10^{-6} SAL. Sterilization by the user is not required.

4.8 PRE-CLINICAL TESTS PERFORMED

In vivo and *In vitro* tests were performed to address irritation, sensitization, cytotoxicity, acute and sub-chronic toxicity, genotoxicity and hemolysis. Results identified the Juliesse™ Injectable Laryngeal Augmentation Implant as a nonirritant, and nontoxic with no concerns for long-term safety.

4.9 SUMMARY

The Juliesse™ Injectable Laryngeal Augmentation Implant is a safe and effective implant used as a space filling material for soft tissue augmentation in laryngeal procedures for vocal fold medialization and augmentation. All syringe components share extensive safety history in medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2006

BioForm Medical, Inc.
c/o Mr. James S. Miller, V.P.
1875 South Grant St.
Suite 110
San Mateo, CA 94402

Re: K060815
Trade/Device Name: Juliesse ™ Injectable Laryngeal Augmentation Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: MIX
Dated: March 24, 2006
Received: March 27, 2006

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060815

3. STATEMENT OF INDICATIONS FOR USE

BioForm's Juliesse is indicated as a resorbable implant material to aid in surgical reconstructions as a space occupying material in laryngeal surgical procedures for vocal fold medialization and augmentation. Juliesse is a temporary implant and resorbs within a period of 3-6 months. The indication as stated above is identical to the BioForm predicate device (injectable laryngeal augmentation implant) being marketed under 510(k) K033398, dated December 12, 2003.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K060815